DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 24 1999

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Thomas C. Pontani, Ph.D.
Cohen, Pontani, Lieberman & Pavane
551 Fifth Avenue
New York, NY 10176

Re: Docket No. 98P-0624/CP1

Dear Dr. Pontani:

This responds to your citizen petition, dated July 24, 1998, submitted on behalf of Schein Pharmaceutical, Inc. and Eon Labs Manufacturing, Inc. (Eon). You request that the Food and Drug Administration (FDA) permit the approval of abbreviated new drug applications (ANDAs) for ticlopidine hydrochloride tablets (ticlopidine) no later than 180 days after June 12, 1998. Your petition was rendered moot by a recent court ruling; moreover, the Agency has now approved all eligible ANDAs for ticlopidine, including that of Eon.

The reference listed drug at issue is Ticlid (NDA 19-979) sponsored by Hoffman-La Roche Inc. (Roche). You request that FDA determine that a May 12, 1998, dismissal in a court action (*Hoffman-La Roche Inc. and Syntex (U.S.A.) Inc. v. Eon Labs Manufacturing, Inc.*, 98 Civ. 2006 (E.D.N.Y. May 12, 1998)) constitutes a "court decision" of noninfringement in patent litigation for purposes of section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the Act). You state that the time to appeal the May 12, 1998, decision expired on June 12, 1998, and that the 180-day exclusivity period should have commenced on that date (Petition at 2).

As you note (Petition at 14), Teva Pharmaceuticals USA, Inc. (Teva) brought a declaratory judgment action against Roche and Syntex on June 8, 1998, in the Northern District of California. As explained below, your petition was rendered moot by a recent court ruling that relates to Teva's declaratory judgment action.

On August 19, 1999, the Court of Appeals for the District of Columbia held that the California district court's August 14, 1998, dismissal of Teva's declaratory judgment action constituted a "court decision" of noninfringement for purposes of section 505(j)(5)(B)(iv) of the Act. *Teva Pharmaceuticals USA, Inc. v. Food and Drug Administration*, No. 99-67, slip op. at 2, 14 (D.C. Cir. August 19, 1999). The California district court's 1998 dismissal occurred over a year prior to the 1999 ruling by the Court of Appeals. Torpharm's exclusivity period, as determined by the Court of Appeals, was therefore already completed, and all otherwise approvable ANDAs referencing Ticlid became immediately eligible for final approval. Four ANDAs for ticlopidine, including one submitted by Eon, received final approval by the Agency on August 20, 1999.

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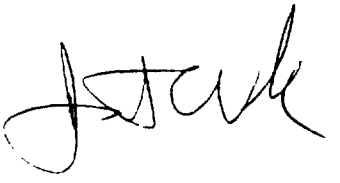
The Agency recently published a proposed rule addressing 180-day generic drug exclusivity (64 FR 42873, August 6, 1999). That proposed rule includes the Agency's interpretation of "court decision" with respect to declaratory judgment actions (64 FR at 42881). If you have further comments pertaining to 180-day generic drug exclusivity, the Agency encourages you to submit them to the Dockets Management Branch as described in the proposed rule.

Sincerely yours,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research